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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,061	04/04/2005	John Sidney	2060.0330002/EKS/MM	7448

26111 7590 08/23/2006

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EXAMINER	
BRISTOL, LYNN ANNE	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/530,061	SIDNEY ET AL.	
	Examiner	Art Unit	
	Lynn Bristol	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *April 4, 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-19 are all the pending claims for this application and subject to lack of unity restriction under 35 U.S.C. 121 and 372.

2. Claims 16, 17 and 19 are directed to non-statutory subject matter under 35 USC 101. The claims recite a "use" of the composition. To advance prosecution, the claims are given the most reasonable interpretation, thus claim 16 reads as a method of preventing a viral infection or cancer and claims 17 and 19 read as a method of treating a viral infection or cancer.

3. Claims 1-19 are drawn to one or more of the peptides in Tables 11-29 of the specification. The Office does not have the resources to examine the scope of embodiments encompassed by, for example, the peptides of Table 11 much less that in addition to Tables 12-29. Thus, in response to this action, Applicants are required to elect up to a total of ten (10) peptides selected from Tables 11-29, and which read on the claims as set forth below. It is noted that the peptides in the specification are not identified by sequence identifier, but Applicants will need to amend the specification and identify which peptides by SEQ ID NO. they elect for examination.

Lack of Unity Restriction

4. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature that appears to link claims 1-19 are peptides or peptides encoded by nucleotides comprising T-cell immunogenic epitopes. Applicants are reminded that because the claims recite "comprising" language, the claims are given the broadest reasonable interpretation in light of the specification. Thus, any T-cell immunogenic (T helper or T cytotoxic) peptide could be encompassed as claimed. Jackson et al. (Current Drug Targets 3:175-196 (2002)) is a general review of the strategies for designing T helper- and T cytotoxic-inducing peptide vaccines, that peptides can be derived from bacteria, viruses, parasites and cancers, combining peptides and MAP systems. Swiniarski et al. (Clinical Immunol. 94:200-211 (2000)) teaches a more specific example of combining CTL peptide epitopes and T helper cell epitopes with Il-12 as a vaccine adjuvant in producing an enhanced immunogenic response to influenza virus infection and extending these observations to cancer therapy. Therefore the technical feature recited in claims 1-19 is not a contribution over the prior art. Accordingly the groups set forth below are not so linked as to form a single general concept under PCT Rule 13.1.

5. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, Claims 1, 3-15, and 18, drawn to a composition comprising one or more peptides from Tables 11-29, a pharmaceutical composition thereof, a vaccine composition thereof, and a diagnostic reagent thereof.

Group 2, Claim 2, drawn to a composition comprising nucleic acids encoding one or more peptides from Tables 11-29.

Group 3, Claim 16, drawn to a method of preventing a viral infection comprising a prophylactic composition comprising one or more peptides from Tables 11-29.

Group 4, Claim 16, drawn to a method of preventing a cancer comprising a prophylactic composition comprising one or more peptides from Tables 11-29.

Group 5, Claim 17 and 19, drawn to a method of treating a viral infection comprising a therapeutic composition comprising one or more peptides from Tables 11-29.

Group 6, Claim 17 and 19, drawn to a method of treating a cancer comprising a therapeutic composition comprising one or more peptides from Tables 11-29.

6. The inventions listed as Groups 1-6 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above in view of the teachings from the reference documents, the groups are not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature shared by Groups 1-6 is not special.

7. Claims 1-19 are drawn to one or more of the peptides in Tables 11-29 of the specification. Applicants are required to select up to a total of ten (10) peptides from Tables 11-29 for examination (MPEP 803.04). **THIS IS NOT AN ELECTION OF SPECIES.** The different peptides are patentably distinct because they are unique

structures composed of different nucleic acid and/or amino acid sequences. The search of any particular sequence is not coextensive with the search of any other different sequence, one specific sequence, or one specific combination of sequences, and a reference against one sequence is not necessarily a reference against any other sequence.

The inventions are distinct and separate for the following reasons:

8. Inventions of Groups 1 and 2 represent distinct and related products, which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. See MPEP § 806.05(j).

The peptides of Group 1 for a T-cell immunogenic epitope are distinct in that each would contain different amino acids which occur naturally or are introduced by mutation, and the products could be generated by synthetic means or subcloning the cDNAs encoding the different epitopes so that the cDNAs are operatively linked for co-expression of an mRNA. The polypeptides would be made by translation of mRNA, and the mRNA would differ for each of the respective polypeptides.

Group 2 is drawn to polynucleotides that are distinct and separate in their nucleotide compositions and each encodes the peptides for T-cell immunogenic epitopes that are distinct in that each would contain different amino acids which occur naturally or are introduced by mutation. The nucleotides would be produced by synthetic means or subcloning the cDNAs encoding the epitopes so that the cDNAs are operatively linked for co-expression of an mRNA.

In the instant case, the nucleic acid claims do not overlap the scope of the peptide claims and vice versa as evidence by the distinct structures and functions of the claimed inventions. A nucleotides structure is comprised of linear, contiguous nucleic acids while a protein's structure comprised of linear, contiguous amino acids that fold into a specific three-dimensional structure; the nucleotides function is to encode a protein while a protein's function is variable, and in this case, for being a T-cell immunogenic epitope. Additionally, the nucleotides and peptides are not obvious variants of each other based on the distinct structures and functions of each as noted above. Lastly, the nucleotides and peptides have materially different functions as noted above.

Because these inventions are distinct for the reasons given above and the search required for Group 1 is not required for Group 2, restriction for examination purposes as indicated is proper.

9. The methods of Groups 3-6 differ in the method objectives, method steps and parameters, intended populations and in the reagents used.

The method inventions of Groups 5 and 6 for treatment and of Groups 3 and 4 for prevention are distinct for the following reasons: treating a patient with an T-cell immunogenic peptide would require different routes of administration, dosing, formulation, sensitivity of detection, etc., and one could not predict biodistribution of the peptides in a subject much less that an outcome of success in the treatment of any viral infection or any cancer in following the same method steps or conditions. Also, because the methods involve providing administering a peptide, the molecule would need to be

formulated in a therapeutically effective composition and depending on the route of administration. The method invention of preventing a viral infection or cancer with a peptide, would seemingly encompass subjects in remission or susceptible to or predisposed to a certain disorder, but requiring that they are free of the specific disorder in order for the disorder to be prevented. Also, because the methods involve providing administering a peptide, the molecule would need to be formulated in a prophylactically effective composition and depending on the route of administration. The amount of a peptide required to achieve a therapeutic effect versus a prophylactic effect would be recognized by one skilled in the art as being distinct and separate. Each of the compositions would differ in the amount of the active ingredient and the adjuvant in addition to any other ingredients encompassed by the claim, in order to obtain a final product having either one of these properties. The method of producing a therapeutic effect versus a prophylactic effect would be recognized by one skilled in the art as being distinct and separate. Each of the methods would differ in the amount of the active agent administered, when and how often the active agent was administered, how the active agent was administered, etc., in order to obtain a method producing one of these properties.

10. Inventions of Group 1 and Groups 3-6 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the

peptides could be used as blocking reagents for non-specific binding of proteins in, for example, Western blot or ELISA, in addition to being used to adsorb binding ligands from samples or to detect binding ligands in assay systems.

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Election of Species

13. If Group 1 is elected, then species (antigen-derived peptide) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie 1) prostate specific antigen (PSA)

Specie 2) prostate specific membrane antigen (PSM)

Specie 3) hepatitis B virus (HBV) antigen

Specie 4) hepatitis C virus (HCV) antigen

Specie 5) malignant melanoma antigen (MAGE)

Specie 6) Epstein Barr virus

Specie 7) human immunodeficiency type-I (HIV-1)

Specie 8) human immunodeficiency type-z (HIV-2)

Specie 9) papilloma virus

Specie 10) Lassa virus

Specie 11) mycobacterium tuberculosis (MT)

Specie 12) p53

Specie 13) murine p53 (mp53)

Specie 14) CEA

Specie 15) HER2/neu

Specie 16) tyrosine kinase related protein (TKP).

Species 1-16 represent a diversity of unrelated antigens, each well recognized in the art as being expressed on different cell types, having different structural proteins,

different cognate ligands and signal interactions. For example, any commercial handbook of biochemistry, microbiology, pathology and/or medicine alone or in combination would disclose the characteristics for each of the species of antigen. In addition, The Human Protein Reference Database (HPRD.org) describes the tissue expression patterns, structural and functional properties and any disease correlates for the some eukaryotic antigens. The species are not obvious variants or overlapping.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 1 generic as to Species 1-16.

14. If any one of Groups 5 or 6 is elected, then species (viral infection or cancer) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie 1) prostate cancer

Specie 2) hepatitis B

Specie 3) hepatitis C

Specie 4) AIDS

Specie 5) renal carcinoma

Specie 6) lymphoma

Specie 7) CMV

Specie 8) chondyloma acuminatum

In the instant case the species of cancer can originate from any number of different cell types (e.g., epithelial, mesothelial or endothelial). Also, the cancers being

associated with different organs are nevertheless, under the influence of different growth factors, hormones, cytokines, etc. Additionally, numerous studies have shown that receptor density and affinity for different biomolecules is highly variable amongst different tissues and organs, in addition to there being differences to the extent to which biomolecules are able to penetrate tissues and organs. This suggests that any method inventions involving administering a therapeutic (or prophylactic) agent in the realm of a cancer, would require different routes of administration, dosing, formulation, sensitivity of detection, etc., and that one could not predict biodistribution of the therapeutic (or prophylactic) agent in a subject much less an outcome of success for treating or preventing all of the listed cancers in following the same method steps or conditions.

With respect to the species of virus, the species do not share a common core structure or function, thus the species are patentably distinct. One of ordinary skill in the art could readily consult any general microbiology textbook describing their different classifications (taxa), genome structures, cell structure and metabolic characteristics, to appreciate that these species are distinct and separate.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 17 generic as to Species 1- 8.

15. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

16. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

17. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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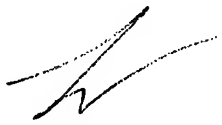

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER